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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/810,377	03/16/2001	Matthew M. Graf	PA-5239-RFB	8787
9896	7590	12/30/2003	EXAMINER	
COOK GROUP PATENT OFFICE P.O. BOX 2269 BLOOMINGTON, IN 47402			HOOK, JAMES F	
			ART UNIT	PAPER NUMBER
			3752	

DATE MAILED: 12/30/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/810,377

Applicant(s)

GRAF ET AL.

Examiner

James F. Hook

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-6 and 10-14 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-6 and 10-14 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 4, 10, and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Coneys. The patent to Parker discloses the recited sheath comprising a shaft 16 extending from a proximal end portion to a distal end portion, a distal tip 12 at the distal end of the shaft, the distal tip section comprising polymeric material 34 containing 35-65% of a radiopaque material such as tungsten, where the shaft is less radiopaque than the distal tip section, the polymeric material can be polyamide, and the tip member was originally a separate member. The patent to Parker discloses all of the recited structure with the exception of using fluorinated ethylene propylene as the polymeric material. The patent to Coneys discloses that it is known in the art that fluorinated ethylene propylene can be used as sleeves in catheters when used in combination with radiopaque materials of varying amounts. It would have been obvious to one skilled in the art to modify the polymeric material in Parker to be made of any suitable plastic for use with catheters including fluorinated ethylene propylene as suggested by Coneys as such is a known equivalent plastic that is used with catheters provided with varying amounts of radiopaque materials as such is a material having more lubricious properties which would allow for easier insertion.

Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Coneys and Hopkins. The patent to Parker discloses all of the recited structure with the exception of stating the size of the tungsten particles used and using FEP for the catheter. The patent to Hopkins discloses the recited use of radiopaque materials such as tungsten in a catheter, where it is known that the particles can be as small as 0.9 microns, which suggests they can be any size larger than 0.9 microns also. It would have been obvious to one skilled in the art to modify the tungsten in Parker to be of a size at least as small as 0.9 microns and larger as such are known particle sizes of tungsten used in radiopaque catheters as suggested by Hopkins as such would be more easily visible. The patent to Coneys discloses that it is known in the art that fluorinated ethylene propylene can be used as sleeves in catheters. It would have been obvious to one skilled in the art to modify the polymeric material in Parker to be made of any suitable plastic for use with catheters including fluorinated ethylene propylene as suggested by Coneys as such is a known equivalent plastic that is used with catheters provided with varying amounts of radiopaque materials as such is a material having more lubricious properties which would allow for easier insertion.

Claims 5, 6, 11, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker in view of Coneys as applied to claims 1, 2, 4, 10, and 13 above, and further in view of Hopkins. The patent to Parker as modified discloses all of the recited structure with the exception of stating the size of the tungsten particles used. The patent to Hopkins discloses the recited use of radiopaque materials such as

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tungsten in a catheter, where it is known that the particles can be as small as 0.9 microns, which suggests they can be any size larger than 0.9 microns also. It would have been obvious to one skilled in the art to modify the tungsten in Parker as modified to be of a size at least as small as 0.9 microns and larger as such are known particle sizes of tungsten used in radiopaque catheters as suggested by Hopkins and such would be more easily visible.

Response to Arguments

Applicant's arguments filed October 14, 2003 have been fully considered but they are not persuasive. Applicant's arguments are directed toward the teachings of Coneys, however, it should be noted that Coneys is merely used to teach the substitution of one type of plastic material for another, all of the rest of the structure is set forth in the base reference. Therefore, Coneys need not teach any other structure other than the use of FEP for catheters, any arguments directed toward added structure shown in Coneys is moot when such is not relied on, only the use of the specific plastic is, where Coneys teaches that FEP can be loaded with radiopaque materials. It is also considered that even if Coneys was considered to require the outer layer such would not destroy the combination when applicant has not claimed the structure using the term consisting of, and the use of comprising allows the references to teach more structure than is required. With respect to the statement that Coneys teaches a different sheath structure such is not persuasive when Coneys is not the base reference relied upon to meet all of the applicant's claimed structure with the exception of using FEP to make the sheath of. Any argument directed toward Coneys structure is immaterial when such is

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merely used to teach the substitution of FEP for the sheath material used. With respect to Hopkins, a similar argument is made toward the teachings of much of the structure of Hopkins, however, Hopkins is only used to teach that radiopaque particles of a certain size are used in applications using radiopaque markers, and not to teach any other structure of the sleeve. Therefore, any argument directed toward the structure of Hopkins being different is immaterial when the only modification being made to the base reference is that of teaching the size of the radiopaque material used in an sheath for detection, the examiner is not replacing the tip of the base reference with the marker of Hopkins but merely teaching that in radiopaque sleeves a certain size of particle may be used.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The patent to Pepin disclosing a state of the art catheter.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

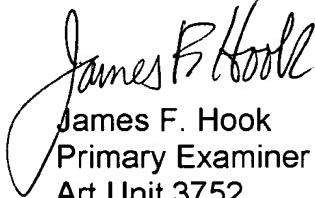
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James F. Hook whose telephone number is (703) 308-2913. The examiner can normally be reached on Monday to Wednesday, work at home Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Mar can be reached on (703) 308-2087. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0861.


James F. Hook
Primary Examiner
Art Unit 3752

JFH